

**REMARKS**

This response addresses the issues raised by the Examiner in the Office Action mailed November 3, 2003. Initially, Applicants would like to thank the Examiner for the careful consideration given in this case. The Claims were 1-4 and 8-11. Claims 1 and 2 have been canceled and Claims 3, 4 and 8 have been amended. Thus, Claims 3, 4 and 8-11 are pending in this case all to more clearly and distinctly claim Applicants' invention. In view of the above amendments and following remarks, Applicants respectfully request entry of the amendments as they place the application in condition for allowance or in better condition for possible appeal.

Claim 3 has been amended to include that the support and the analyte is within the electric field. Support for currently amended Claim 3 appears, for example, in the specification at page 9, lines 9-4. Claims 4 and 8 have been amended to depend on currently amended Claim 3. Accordingly, it is respectfully submitted that no new matter has been added by the amendments.

**Claim Objections**

The Examiner objects to Claims 1-3 because of certain language informalities, as noted by the Examiner. Claims 1-2 have been canceled and thus render these objections moot. In regards to Claim 3, Applicants have amended Claim 3 to address these concerns of the Examiner. Reconsideration of these objections are respectfully requested.

Applicants have amended Claims 4 and 8 to be dependent on Claim 3. Support for currently amended Claim 4 appears, for example, in the specification at paragraph 0038. Support for currently amended Claim 8 appears, for example, in the specification at paragraph 0063. Accordingly, it is respectfully submitted that no new matter has been added

by the amendments. Thus, reconsideration of these objections are respectfully requested.

**Rejection Under 35 U.S.C. § 112, Second Paragraph**

The Examiner rejects Claims 2 and 3 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. In particular, the Examiner has pointed out that Claims 2 and 3 are vague and indefinite in view of step (2). The Examiner asserts that it is unclear if the electric field support is between the support on which the double stranded DNA recognizing substance is immobilized and the analyte and how the double stranded DNA present in an analyte can be directed toward the double stranded DNA recognizing substance immobilized on the support. Applicants respectfully traverse this rejection.

Since Claim 2 has been canceled, Applicants will address Examiner's rejection with regards to Claim 3. In order to expedite prosecution, Claim 3 has been amended to clarify that the support and the analyte is within the electric field. Support for currently amended Claim 3 appears, for example, in the specification at paragraph 0049. We disagree with the Examiner that Claim 3 is vague and indefinite in view of step (2).

In the present invention, the electric field is applied between the support on which the double stranded DNA recognizing substance is immobilized and the analyte. An anode is placed on the side of the support on which double stranded DNA recognizing substance is immobilized or making the support itself the anode and placing a cathode with the analyte containing double stranded DNA. See the Specification at paragraph 0049. The electric field is applied between the anode and cathode. See Specification at paragraph 0049. The purpose of the electric field is to move and concentrate the double stranded DNA present in analyte toward the double stranded DNA recognizing substance immobilized on the support. The electric field is applied in order to achieve the concentration of the double stranded DNA and thus shorten the detection time and increase the sensitivity. This amendment is not intended to narrow the scope of the claims. Therefore, Applicants respectfully request withdrawal of

the rejection under 35 U.S.C. § 112, second paragraph.

The Examiner also rejects Claims 2 and 3 as vague and indefinite in view of steps (1) and (2) of the claims. The Examiner asserts that steps (1) and (2) do not correspond with each other because step (1) has the analyte contacting the double stranded DNA recognizing substance immobilized on a support so it is unnecessary to require to direct double stranded DNA present in an analyte toward the double stranded DNA recognizing substance immobilized on the support. Applicants respectfully traverse this rejection.

As stated above, since Claim 2 has been canceled, Applicants will address Examiner's rejection with regards to Claim 3. Presently amended Claim 3 clarifies that the support and the analyte is within the electric field. We disagree with the Examiner that Claim 3 is vague and indefinite in view of steps (1) and (2).

The present invention discloses a method of analyzing double stranded DNA present in an analyte comprising contacting the analyte with a double stranded DNA recognizing substance immobilized on a support and then applying an electric field encompassing the substrate and analyte to direct the double stranded DNA in the analyte toward the double stranded DNA recognizing substance. In the present invention, the signal/noise ratio is increased by applying an electric field between the double stranded DNA recognizing substance immobilized on the support and the double stranded DNA present in the analyte to promote binding. See Specification at paragraph 0011. The purpose of step (2) is to promote binding and increase the signal/noise ratio between the double stranded DNA in an analyte and the double stranded DNA recognizing substance immobilized on a supports so that the method of analyzing double stranded DNA enables a quick and high sensitive detection of a gene and polymorphism. Since steps (1) and (2) do correspond to each other, currently amended Claim 3 is not vague and indefinite in view of steps (1) and (2). Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

The Examiner rejects Claim 8 as vague and indefinite because it is unclear if “a reaction system” has a complex formed by the double stranded DNA and the double stranded DNA recognizing substance. The Examiner further states that if “a reaction system” does not have a complex formed by the double stranded DNA and the double stranded DNA recognizing substance, the insertion agent is the reaction system cannot insert into a double stranded DNA. Applicants respectfully traverse this rejection.

As stated above, Applicants have amended Claim 8 to be dependent on Claim 3. The present invention discloses a method of analyzing double stranded DNA present in an analyte comprising (1) contacting the analyte with a double stranded DNA recognizing substance immobilized on a support and then (2) applying an electric field encompassing the substrate and analyte to direct the double stranded DNA in the analyte toward the double stranded DNA recognizing substance. The present invention also discloses that an electric field is then applied in a direction opposite to the direction of the electric field applied in (2), to remove the double stranded DNA that were not bound with the double stranded DNA recognizing substance so that the double stranded DNA bound to the double stranded DNA recognizing substance can be measured. In the measuring step of the present invention, an insertion agent that recognizes double stranded DNA is added to a reaction system and the double stranded DNA present in the analyte is measure by detecting the insertion agent inserted into the double stranded DNA. Here, the reaction system has a complex formed by the double stranded DNA and the double stranded DNA recognizing substance. The purpose of the DNA insertion agent is so that the DNA in an analyte can be measured without complicated labeling. See Specification at paragraph 00063. A DNA intercalator can be used as a DNA insertion agent for detecting the double stranded DNA that were bound to the double stranded DNA recognizing substance. Note that the double stranded DNA recognizing substance is not the same as an insertion agent, such as DNA intercalator. Thus, currently amended Claim 8 is not vague and indefinite as to the term “a reaction system”. Accordingly, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112, second paragraph.

**Rejection Based On Vinayagamoorthy Under 35 U.S.C. § 102 (b)**

The Examiner rejects previously pending Claims 1 and 4 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 5,912,129 to Vinayagamoorthy et al. as applied to currently amended Claim 3. Applicants respectfully traverse this rejection.

The Examiner asserts that Vinayagamoorthy teaches a process of amplifying a DNA by a polymerase chain reaction utilizing a polymerase enzyme. The Examiner also states that Vinayagamoorthy teaches fixing a solid medium, such as a magnetic substrate coated with anti-DNA antibody, within a container where the solid medium has a surface that binds nucleic acid. The Examiner further asserts that Vinayagamoorthy discloses contacting the analyte having DNA with a double stranded DNA recognizing substance immobilized on a support and introducing into the container a first liquid medium. The Examiner then asserts that since Vinayagamoorthy teach that a single stranded DNA denatured from the double-stranded DNA bound to anti-DNA antibody is amplified and is detected by dot blot, Vinayagamoorthy discloses to indirectly qualitatively measure double stranded DNA bound to the double stranded DNA recognizing substance by detecting amplified PCR product. Applicants respectfully disagree.

For a rejection to be sustained under 35 U.S.C. § 102 (b) each and every element of the claimed invention must be disclosed in the cited prior art. As stated above, currently amended claim 3 discloses a method of analyzing a double stranded DNA present in an analyte comprising the following steps: (1) contacting the analyte with a double stranded DNA recognizing substance immobilized on a support, (2) applying an electric field between the support on which the double stranded DNA recognizing substance is immobilized and the analyte, to direct the double stranded DNA present in an the analyte toward the double stranded DNA recognizing substance immobilized on the support, (3) applying an electric field in a direction which is opposite to the direction of the electric field applied in step (2),

and (4) measuring the double stranded DNA bound to the double stranded DNA recognizing substance, where the support and the analyte is within the electric field.

Vinayagamoorthy teaches a process of amplifying a DNA by a polymerase chain reaction utilizing a polymerase enzyme. However, Vinayagamoorthy does not teach the steps of applying an electric field between the support on which the double stranded DNA recognizing substance is immobilized and the analyte, to direct the double stranded DNA present in the analyte toward the double stranded DNA recognizing substance immobilized on the support, applying an electric field in a direction which is opposite to the direction of the electric field applied in the previous, and measuring the double stranded DNA bound to the double stranded DNA recognizing substance, where the support and the analyte is within the electric field. Accordingly, Vinayagamoorthy does not disclose each and every claim element of the claimed invention. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 102 (b) be reconsidered and withdrawn.

**Rejection Based On Vinayagamoorthy Under 35 U.S.C. § 102 (b)**

The Examiner rejects previously pending Claim 2 under 35 U.S.C. § 102 (b) as being anticipated by U.S. Patent 4,868,111 to Bujard et al. Applicants respectfully traverse this rejection.

For a rejection to be sustained under 35 U.S.C. § 102 (b) each and every element of the claimed invention must be disclosed in the cited prior art.

As discussed above, Applicants have canceled Claim 2 which renders this rejection moot. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102 (b).



**Rejection Based On Vinayagamorthy Further In View of Piunno Under 35 U.S.C. §**

**103 (a)**

The Examiner rejects Claims 8, 9, and 11 under 35 U.S.C. § 103 (a) as being unpatentable over Vinayagamorthy as applied to Claims 1 and 4 above, and further in view of Piunno et al. Applicant respectfully traverse this rejection.

The Examiner concedes that Vinayagamorthy do not disclose measuring the double stranded DNA in the complex formed by the double stranded DNA present in the analyte and the double stranded DNA recognizing substance by detecting the insertion agent inserted into the double stranded DNA using a fluorescence method as recited in Claims 8, 9 and 11 but the Examiner refers to Piunno to teach this deficiency in Vinayagamorthy. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to have measured the double stranded DNA in the complex formed by the double stranded DNA present in the analyte and the double stranded DNA recognizing substance by detecting the insertion agent inserted into the double stranded DNA. Applicants respectfully disagree.

To establish obviousness of a claimed invention, all claim elements must be disclosed, taught or suggested by the prior art. We agree with the Examiner that Vinayagamorthy does not teach that to have measured the double stranded DNA in the complex formed by the double stranded DNA present in the analyte and the double stranded DNA recognizing substance by detecting the insertion agent inserted into the double stranded DNA.

Piunno teaches an optical biosensor by synthesizing single-stranded deoxyribonucleic acid thymidylic acid icosanucleotides on the surfaces of derivatized quartz optical fibers. See abstract. Piunno also discloses that hybridization on the optical fiber was detected by the use of the fluorescent DNA stain ethidium bromide. However, Piunno does not disclose a method of analyzing a double stranded DNA present in an analyte where the support and the

analyte is within the electric field.

The present invention claims a method of analyzing a double stranded DNA present in an analyte comprising contacting the analyte with a double stranded DNA recognizing substance immobilized on a support. Then applying an electric field between the support on which the double stranded DNA recognizing substance is immobilized and the analyte, to direct the double stranded DNA present in the analyte toward the double stranded DNA recognizing substance immobilized on the support. The present invention also claims applying an electric field in a direction which is opposite to the direction of the electric field applied in the previous step, and measuring the double stranded DNA bound to the double stranded DNA recognizing substance where the support and the analyte is within the electric field.

Vinayagamoorthy does not disclose a method of analyzing a double stranded DNA present in an analyte where the support and the analyte is within the electric field. Further, Piunno does not disclose this deficiency of Vinayagamoorthy. Thus, the Applicants believe that the amended invention is not obvious over the teaching of Vinayagamoorthy in view of Piunno since Vinayagamoorthy and/or Piunno does not teach, disclose or suggest the present claims. Moreover, one skilled in the art would find nothing in Vinayagamoorthy or Piunno alone or in combination that would disclose, teach or suggest the claimed invention or any reason for making it. Further, there is no motivation to combine the references in such a way to get the claimed invention. Therefore, an obvious rejection under 35 U.S.C. §103 (a) is improper.



**Rejection Based On Vinayagamorthy Further In View of Liu Under 35 U.S.C. § 103**

**(a)**

The Examiner rejects Claims 8-10 under 35 U.S.C. § 103 (a) as being unpatentable over Vinayagamorthy as applied to Claims 1 and 4 above, and further in view of Liu et al. Applicant respectfully traverse this rejection.

The Examiner concedes that Vinayagamorthy do not disclose measuring the double stranded DNA in the complex formed by the double stranded DNA present in the analyte and the double stranded DNA recognizing substance by detecting the insertion agent inserted into the double stranded DNA by electrochemical means but the Examiner refers to Liu to teach this deficiency in Vinayagamorthy. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time of the invention to have measured the double stranded DNA in the complex formed by the double stranded DNA present in the analyte and the double stranded DNA recognizing substance by detecting the insertion agent inserted into the double stranded DNA. Applicants respectfully disagree.

To establish obviousness of a claimed invention, all claim elements must be disclosed, taught or suggested by the prior art. We agree with the Examiner that Vinayagamorthy does not teach that to have measured the double stranded DNA in the complex formed by the double stranded DNA present in the analyte and the double stranded DNA recognizing substance by detecting the insertion agent inserted into the double stranded DNA.

Liu discloses volammetric determination of sequence-specific DNA by electroactive intercalator on graphite electrode. However, Liu does not disclose a method of analyzing a double stranded DNA present in an analyte where the support and the analyte is within the electric field. Further, Liu does not disclose this deficiency of Vinayagamorthy. Thus, the Applicants believe that the amended invention is not obvious over the teaching of Vinayagamorthy in view of Liu since Vinayagamorthy and/or Liu does not teach, disclose

or suggest the present claims. Moreover, one skilled in the art would find nothing in Vinayagamoorthy or Liu alone or in combination that would disclose, teach or suggest the claimed invention or any reason for making it. Further, there is no motivation to combine the references in such a way to get the claimed invention. Therefore, an obvious rejection under 35 U.S.C. §103 (a) is improper.

In view of the remarks presented herein, it is respectfully submitted that the present application is in condition for final allowance and notice to such effect is requested. If the Examiner believes that additional issues need to be resolved before this application can be passed to issue, the undersigned invites the Examiner to contact him at the telephone number provided below.

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Respectfully submitted,

By

  
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